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10/593,023

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EXAMINER

OCHYLSKI, RYAN M

ART UNIT

PAPER NUMBER

1743

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/593,023 | WU ET AL. | |
| | Examiner | Art Unit | |
| | RYAN OCHYLSKI | 1743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,3-15 and 17-32 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,3-15 and 17-32 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. This is a FINAL Office Action in response to Applicant's reply of January 6, 2012, which was in reply to a non-final Office Action mailed on October 7, 2011. Claims 1 and 17 have been amended, Claim 32 has been added, and no Claims have been newly-canceled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 4-11, and 13-14, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryner et al. (US 7,585,451 B2 hereinafter Bryner) in view of Weinberg et al. (US 2006/0135020 A1, hereinafter Weinberg).

6. Claims 15, 18-20, and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryner.

7. The Examiner notes that the subject matter in the Independent Claims (i.e. that the gap between the orifice and electrode is between about 1 millimeter and about 10 millimeters and that the electric voltage applied to the electrode is between about 20 kV and 40 kV) has been accorded a filing date of March 31, 2005, since these limitations first appear in PCT/US20005/010886, of which the instant application is a national stage entry; these limitations do not appear in Provisional Application 60/558,482, to which the PCT claims priority. The Examiner additionally notes that because at least one of these limitations appear in each Independent Claim, all pending claims are currently accorded the March 31, 2005 filing date as well.

8. Note that Claims 1, 3-14, and 32 are directed towards an apparatus and as such will be examined under such conditions. The material worked upon or the process of

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using the apparatus are viewed as recitation of intended use and are given little patentable weight (Please see MPEP 2114 R1-2115 R2 for further details). Specifically, the Examiner notes that Claims 4-10 are apparatus claims that merely recite material used in the apparatus, and thus do not further limit the apparatus, and the rejection of Claims 4-10 below should not be taken as an indication that the material used in Claims 4-10 are being given patentable weight.

9. Regarding Claims 1, 4-10, and 15, Bryner teaches in **Figure 2** a method and apparatus capable of containing the materials recited in currently-pending claims 4-10 for fabricating oriented polymer fibers comprising:

(a) positioning an electrode (**Items 140 and/or 142**) near an orifice (**Item 104**) of a dispenser (**Item 102**) containing a metastable electrically charged polymer dispersion (“the polymer solution is electrically conductive...” Column 3 Lines 12-28)

the dispenser including a proximal end and a distal end, wherein the proximal end defines an orifice, and wherein the electrode is positioned near the proximal end of the dispenser defining the orifice to form a gap (**Item DED**) there between, and wherein the gap between the proximal end of the dispenser defining the orifice and the electrode is between about 1 millimeter and about 10 millimeters

(“...0.01 to about 25 cm...” Column 3 Lines 47-65, which completely encompasses and therefore clearly overlaps the claimed range; also note the specific value of a 12.7 mm gap recited in the Table in Column 5);

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(b) electrically pulling the polymer dispersion from the orifice by applying electric voltage to the electrode, wherein the electric voltage applied to the electrode is between about 20 kV and 40 kV

("electrode can have a significant voltage... spinneret and the electrode can have the same voltage but with different polarities... voltage differential between the electrode and the spinneret is in the range of about 1 to about 100 kV" Column 4 Lines 2-17, which completely encompasses and therefore clearly overlaps the claimed range -- i.e. in the case where the electrode has a 20-40 kV voltage applied thereto, the spinneret would have a negative voltage of 20-40 kV voltage applied thereto, respectively, resulting in the range of a 40-80 kV voltage differential), and

(c) collecting the oriented polymer fibers at a collector (**Item 110**) separated from the gap, and allowing the electropulled dispersion to solidify to form the oriented polymer fibers

("electric field combined with the charge on the polymer stream provides spreading forces which act on the fibers and fibrils formed therein, causing the web to be better dispersed and providing for very uniform web laydown on the collection surface of the collector" Column 3 Lines 6-11).

Additionally, since Bryner's method and apparatus meet all the limitations of Claim 15, the Examiner considers that Bryner's fibers would be oriented, owing at least in part to the applied electric field.

10. Further regarding Claims 1 and 15, Bryner teaches that the dispenser is directly connected to a source of electric potential at the proximal end of the dispenser near the orifice for charging the polymer dispersion (the situation in which the spinneret has the oppositely charged polarity of the electrode in Column 4 Lines 4-17 as applied above, and shown by Figure 2, in which the thick line moving upward from the "High Voltage" turns 90° at a point upward past the reference character "e" and extends into contact with the lower half of the spinneret 102), thereby electrically charging the metastable dispersion inside the dispenser so that the dispersion is pulled by the oppositely-charged electrode through the dispenser.

11. Specifically regarding Claims 1 and 32, Bryner is silent on whether the source of electric potential could be directly connected to the dispenser at the proximal end of the dispenser near the orifice and also directly contacting the metastable polymer dispersion inside the dispenser.

In analogous art pertaining to electrospinning, Weinberg teaches in Figure 3, [0018], and [0050] that a source of electric potential is connected to a dispenser at the proximal end near the orifice thereof and that it also directly contacts the spinning material for the benefit of providing a charge to the spinning material so that it can be drawn toward a collector.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to apply a source of electric potential as per Weinberg to

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Bryner for the benefit of providing a charge to the spinning material so that it can be drawn toward a collector.

12. Regarding Claims 11 and 27, Bryner teaches that the collector is grounded ("the collection belt is grounded" Column 4 Lines 28-29).

13. Regarding Claims 13 and 28, Bryner teaches that the orifice is a capillary tip ("die tip may be in the form of a capillary" Column 2 Lines 53-58).

14. Regarding Claims 14 and 29, the Examiner considers Bryner's disclosure that the nanofibers formed as per Column 5 Lines 1-25 have diameters from about 100 to about 700 nanometers to be evidence that Bryner's orifice has a diameter between about 10 nanometers and 100 micrometers.

15. Regarding Claims 18 and 20, Bryner teaches that the metastable polymer dispersion comprises at least one polymer and a liquid phase made by dispersing the polymer in the liquid phase ("The polymer solution is prepared by selecting a solvent suitable to dissolve the polymer" Column 3 Lines 21-22).

16. Regarding Claim 19, Bryner teaches that the liquid phase comprises a plurality of liquids ("The polymer solution can be mixed with additives including any resin compatible with an associated polymer, plasticizer, ultraviolet ray stabilizer, crosslink

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agent, curing agent, reaction initiator, electrical dopant, etc.” Column 3 Lines 23-26, at least of which the Examiner considers to obviously be at least a second liquid in the liquid phase).

17. Regarding Claim 30, Bryner’s Column 4 Lines 2-17 discloses that the potential difference between the spinneret and the electrode is caused by the same voltages in each, but with different polarities in each, with an overall total voltage differential between 1 to about 100 kV, such that Bryner’s embodiment clearly overlaps the claimed 30 kV being applied to the electrode.

18. Regarding Claim 31, Bryner teaches that the spinneret and the collector are separated by between about 10 to about 50 cm, which, given the gap between the orifice and electrode being between about 1 millimeter and about 10 millimeters (as applied to Claim 1 above), clearly overlaps the claimed range of about 10 centimeters to 30 centimeters between the gap and the collector.

The Examiner also notes that the Table in Column 5 recites Die to Collector Distances of 30 cm, and orifice to electrode gaps of no more than 3 cm.

19. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryner and Weinberg, as applied to Claim 1 above, and in view of Lee et al. (US 2002/0122840 A1 hereinafter Lee).

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20. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryner, as applied to Claim 15 above, and in view of Lee.

21. Regarding Claims 3 and 17, Bryner teaches a source of electric potential as applied above.

However, Bryner and Weinberg are silent on whether the source of electric potential is a direct current battery.

In analogous art pertaining to electrospinning, Lee teach that is known to use a direct current battery as a source of electric potential to yield the predictable result of piling electrospun fibers ("The high voltage generator 40 outputs DC voltage ... and has an anode output terminal ... and a cathode output terminal" [0052] ; also see [0054]).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to use a direct current batter as per Lee as a the source of electric potential in Bryner's process to yield the predictable result of piling electrospun fibers.

22. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryner and Weinberg, as applied to Claim 1 above, and in view of Childs (US 2,338,570 A, hereinafter Childs).

23. Regarding Claim 12, the previous combination teaches the general apparatus as applied above, but is silent on materials of construction for the spinnerets/dispensers.

In analogous art pertaining to electrospinning, Childs teaches that dispensers are made of glass for the benefit of providing an electrically insulating material that prevents buildup of metastable dispersion on the orifice (Column 6 Lines 53-75).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to use glass as per Childs as the material of construction for the previous combination's spinnerets for the benefit of providing an electrically insulating material that prevents buildup of metastable dispersion on the orifice.

24. Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryner, as applied to Claim 18 above, and in view of Chu et al. (US 2003/0054035 A1 hereinafter Chu).

25. Regarding Claim 21, Bryner teaches the general method as applied above, but is silent on whether the polymer could first be dissolved in a solvent to make a polymer solution, with the polymer solution then being dispersed in the liquid phase.

In analogous art pertaining to electrospinning, Chu teaches pre-dissolving material prior to adding to a larger liquid phase is a known technique that yields the predictable result of better dispersion of the additive in the larger liquid phase ("In loading the additives, the additive may need to be dissolved in a solvent..." [0129]).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to apply the known pre-dissolving technique as per Chu to

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the polymer addition of Bryner to achieve the predictable result of better dispersion of the polymer in the larger solvent phase.

26. Regarding Claim 22, Bryner teaches the general method as applied above, but is silent on whether the polymer could be poly(lactic acid-co- glycolic acid).

In analogous art pertaining to electrospinning, Chu teaches that the polymer is poly(lactic acid-co- glycolic acid) for the benefit of forming membranes that retains significant flexibility and never becomes brittle or develops cracks when twisted in a frozen state, and returns to full flexibility at room temperature (“A PLGA ... membrane [comprising electrospun submicron fibers] was produce by a process similar to Example 1”) [0232]-[0233]).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to apply Chu to Bryner for the benefit of forming membranes that retains significant flexibility and never becomes brittle or develops cracks when twisted in a frozen state, and returns to full flexibility at room temperature.

27. Regarding Claims 23 and 24, Bryner teaches the general method as applied above, but is silent on whether the metastable dispersion further comprises a compound decreasing the stability of the metastable polymer dispersion, namely sodium chloride.

In analogous art pertaining to electrospinning, Chu teaches that a polymer dispersion comprises a compound, namely sodium chloride, for decreasing the stability of the metastable polymer dispersion for the benefit of facilitating an electrospinning

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process (“The conducting fluid can optionally contain a salt which creates an excess charge effect to facilitate the electrospinning process ... includ[ing] NaCl” [0191]).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to apply Chu to Bryner for the benefit of facilitating an electrospinning process.

28. Regarding Claim 25, Bryner teaches the general method as applied above, but is silent on whether the metastable dispersion further comprises biologically active molecules.

In analogous art pertaining to electrospinning, Chu teaches that a polymer dispersion comprises biologically active molecules for the benefit of imbuing a formed nanofiber web with biologic functionality (“calcium hydroxyapatite can also be incorporated [into the conducting fluid” [0191]; also “one or more cell culture additives can be incorporated into the conducting fluid” [0191] as defined in [0130]).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to apply Chu to Bryner for the benefit of imbuing the formed nanofiber web with biologic functionality.

29. Regarding Claim 26, Bryner teaches the general method as applied above, but is silent on whether the metastable dispersion further comprises at least one surfactant.

In analogous art pertaining to electrospinning, Chu teaches that a polymer dispersion comprises at least one surfactant for the benefit of allowing additives to be

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added more easily to incompatible solvents ("In loading the additives, the additive may need to be dissolved in a solvent that may not be compatible with the solvent used in the electrospinning process. A block copolymer, acting as a surfactant, can be used to circumvent this difficulty" [0129]).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to apply Chu to Bryner for the benefit of allowing additives to be added more easily to incompatible solvents.

Response to Arguments

30. Applicant's arguments with respect to the newly-amended portion of Claim 1 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

31. Applicant's arguments filed January 6, 2012 have been fully considered but they are not persuasive.

32. With respect to the question of whether Bryner's fibers can be considered oriented, the Examiner first notes that Applicant's definition of oriented polymer fiber appears to refer to individual fibers independent of the larger fiber mass, as per the definition in [0018] of the instant specification: "polymer is referred to as "oriented" if the axis [sic, should be axes] of main chains of the macromolecules are arrayed predominantly along one direction, and the axis [sic, should be axes] are therefore

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substantially parallel to each other.” Therefore, a randomly-oriented fiber mat could still be made of oriented individual fibers and satisfy the instant claim preambles reciting “oriented polymer fibers” -- a case that the Examiner believes applies to the Bryner reference and combinations based thereon.

For instance, see Reneker et al., J. Appl. Phys., 87(9), 4531, 2000 reciting the extreme likelihood of fibers being electrospun at an electrical potential difference of around 20 kV. Namely, see the final partial paragraph of page 4532, wherein Figure 1 shows that the fibers are being laid down in a randomly-oriented mat, with the section “D. Longitudinal strain rate and molecular orientation” across pages 4545-4546 showing that these conditions produced molecular orientation as evaluated by a test in which the conditions produced a value many orders of magnitude above a threshold indicating molecular orientation.

Thus, as best as the Examiner can ascertain, a voltage difference of 20 kV (a difference that exists within Bryner’s operating range) is so likely to create oriented fibers so as to be an inherent effect of electrospinning/blowing unless specific measures are taken to the contrary. Since Bryner does not disclose specific measures to the contrary being taken, the Examiner maintains that it is reasonable to consider Bryner’s fibers oriented

If Applicant intends to recite a form of orientation besides that of individual fibers on the molecular level, Applicant should amend the Claims accordingly.

Conclusion

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RYAN OCHYLSKI whose telephone number is 571-270-7009 and whose direct fax number is 571-270-8009. The examiner can normally be reached on Monday through Thursday and every other Friday from 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rmo

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 1743